

DETAILED ACTION

1. The amendment filed on November 13, 2009 have been received and considered. By these amendments, claim 1 is amended, claim 7 is cancelled, claim 29 is added, and claims 1-6, 8-13, and 15-29 are now pending in the application, with claims 15-24 and 26-28 being previously withdrawn.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-5, 8-13, 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westlund et al. (U.S. Patent No. 6,643,550). Regarding claim 1, Westlund discloses a medical electrical lead comprising a component 100 including a surface and a groove 205/207/240 formed in the surface and including an inherent depth, and a conductor 195, including an inherent pre-weld diameter, extending within the lead and including a portion positioned and welded within the groove of the component (see Figures 6 and 7 and col. 5, ln. 50-65). Figures 10C and 10D further show a cutaway view of conductor 195 that illustrates the conductor comprising a plurality of wire strands cabled together. Further, Westlund discloses that suitable welding techniques for welding conductors, such as conductor 195, includes resistance welding (see col. 7, ln. 63-65). However, Westlund fails to disclose that the pre-weld diameter of the conductor is greater than the depth of the groove. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the pre-weld diameter of the conductor to be greater than the depth of the groove, since it

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has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Alternatively, one of ordinary skill in the art would recognize that the pre-weld diameter of the conductor may be smaller than, larger than, or the same size as the depth of the groove. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to choose from these three finite, identified solutions when determining the appropriate ration between the diameter of the conductor and the depth of the groove.

4. Regarding claim 2, it can be seen from Figures 1 and 8 of Westlund that the surface has a curved profile.

5. Regarding claims 3-5, it can be seem from Figures 1 and 6-8 of Westlund that the component 100 comprises a substantially tubular body and the surface includes inner and outer diameters.

6. Regarding claim 8, Westlund discloses that the conductor may be a coil (see Figures 6 and 10D).

7. Regarding claims 9 and 25, it can be seen from Figure 6 of Westlund that the groove extends approximately aligned with a longitudinal axis of the component.

8. Regarding claim 10, it can be seen from Figure 10D of Westlund that the groove 207 may extend approximately transverse to a longitudinal axis of the component.

9. Regarding claim 11, it can be seen from Figure 10D of Westlund that the groove 207 may spiral about a portion of a circumference of the surface.

10. Regarding claims 12 and 13, it can be seen from Figure 10D of Westlund that the groove 207 includes a generally U-shaped cross-section. The Examiner takes the position that a generally U-shaped groove has an approximately semi-circular cross-section. Furthermore, as a U-shape is simply a smoothed V-shape, the Examiner takes the position that the groove of Westlund has an approximately V-shaped cross section.

11. Regarding claim 29, Westlund discloses a medical electrical lead comprising a component 100 comprising a substantially tubular body including a surface and a groove 205/207/240 formed in the surface and including an inherent depth, and a conductor 195, including an inherent pre-weld diameter, extending within the lead and including a portion positioned and welded within the groove of the component (see Figures 6 and 7 and col. 5, ln. 50-65). The Examiner respectfully submits that Westlund illustrates in Figure 10B that the component 100 has a substantially tubular body having an inner surface and a groove formed in the inner surface, as shown in the reproduction of Figure 10B below:

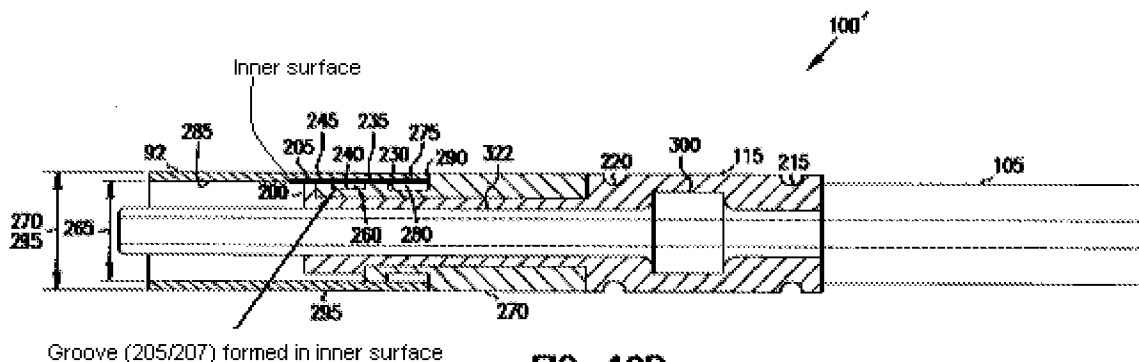


FIG. 10B

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Furthermore, Figures 10C and 10D of Westlund show a cutaway view of conductor 195 that illustrates the conductor comprising a plurality of wire strands cabled together; and Westlund discloses that suitable welding techniques for welding conductors, such as conductor 195, includes resistance welding (see col. 7, ln. 63-65). However, Westlund fails to disclose that the pre-weld diameter of the conductor is greater than the depth of the groove. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the pre-weld diameter of the conductor to be greater than the depth of the groove, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Alternatively, one of ordinary skill in the art would recognize that the pre-weld diameter of the conductor may be smaller than, larger than, or the same size as the depth of the groove. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to choose from these three finite, identified solutions when determining the appropriate relation between the diameter of the conductor and the depth of the groove.

12. Claims 1-6, 8, 9, 12, 13, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ley et al. (U.S. Patent No. 6,912,423) in view of Bush et al. (U.S. Patent No. 5,385,578). Regarding claim 1, Ley discloses a medical electrical lead comprising a component 100 including a surface and a groove 102 formed in the surface, a conductor 106 extending within the lead, including a plurality of wire strands cabled together, and a portion positioned within the component, wherein the groove includes a depth and the portion of the conductor positioned within the groove includes

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a pre-weld diameter, the pre-weld diameter being greater than the depth of the groove (see Figures 9 and 10 and col. 5, ln. 41-56). However, Ley fails to disclose a resistance weld formed between the portion of the conductor and the component. Bush teaches the utilization of a resistance weld formed between conductors and lead components in order to minimize the bulk of the connection (see col. 7, ln. 24-26 and 31-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize a resistance weld between the conductor and component of Ley, as taught by Bush, in order to minimize the bulk of the connection.

13. Regarding claim 2, it can be seen from Figure 9 of Ley that the surface has a curved profile.

14. Regarding claims 3-5, it can be seen from Figures 9 and 10 of Ley that the component comprises a substantially tubular body and the surface includes inner and outer diameters. Further, Ley discloses that the component includes an outer electrode surface 128 (see Figure 8).

15. Regarding claim 6, Ley discloses the invention essentially as claimed, but fails to specifically disclose that the outer electrode surface includes a titanium nitride coating. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Ley in view of Bush with a titanium nitride coating on the outer electrode surface since it was known in the art that titanium nitride coatings are utilized to enhance biocompatibility and improve electrical characteristics.

16. Regarding claim 8, Ley discloses that the conductor may be a coil (see col. 5, ln. 29-32).

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17. Regarding claims 9 and 25, it can be seen from Figure 9 of Ley that the groove may extend approximately aligned with a longitudinal axis of the component.

18. Regarding claims 12 and 13, it can be seen from Figure 10 of Ley that the groove 102 includes a generally U-shaped cross-section. The Examiner takes the position that a generally U-shaped groove has an approximately semi-circular cross-section. Furthermore, as a U-shape is simply a smoothed V-shape, the Examiner takes the position that the groove of Westlund has an approximately V-shaped cross section.

Response to Arguments

19. An interview was initiated by the Examiner on February 3, 2010 with Attorney Carol F. Barry and on February 10, 2010 with Attorney Reed Duthler, to discuss the above rejections and propose amendments to the claims to place them in a better form for allowance. These interviews did not result in allowance of the claims and are summarized in the attached Examiner Initiated Interview Summary.

20. Further, Applicant's arguments filed November 13, 2009 have been fully considered but they are not persuasive. Regarding the rejection of the claims as being unpatentable over Westlund, the Applicant argues that chamfer 207 of Westlund is described as included in sleeve 115, which has been characterized as a molded insulative hard polymer and it is unclear how conductor 195 could be resistance welded in chamfer 207. The Examiner respectfully submits that Westlund clearly states at column 7, lines 62-65, that "the conductor is welded inside the partial chamfer 240" and "suitable welding techniques include, but are not limited to, laser welding, resistance welding or butt welding." Therefore, the Examiner respectfully submits that Westlund

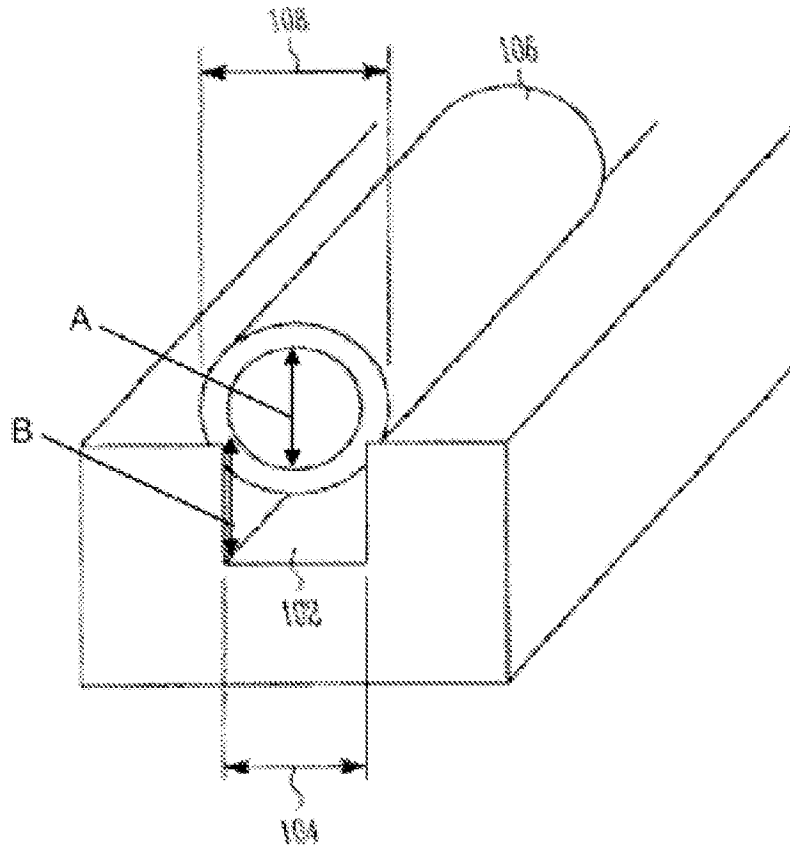
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discloses that a resistance weld may be formed between the conductor and the component. Further, with respect to the Examiner's contention that it would be obvious to make a pre-weld diameter of the conductor to be greater than the depth of the groove, the Applicant argues that the pre-weld diameter of the conductor of Westlund could not be greater than the depth of the groove because "when a conductor is a solid wire conductor and is larger than the depth of a groove, the point of contact between a resistance welding electrode and the round conductor forms the point of greatest resistance to the weld current...creat[ing] a weld pool on the surface of the conductor that is outside the groove...prevent[ing] formation of an adequate weld pool at the points of contract between the conductor and the groove cause the weld to fail." However, the Examiner respectfully submits that the Applicant has failed to provide support for such an assertion, and further has failed to disclose how the present invention differs from this characterization. Furthermore, the Examiner respectfully submits that because the conductor of Westlund, as shown in Figures 10C and 10D, is not in fact "a solid wire conductor," the Applicant's arguments are moot. As such, the Examiner submits that the claims are unpatentable over Westlund.

21. Further, regarding the rejection of the claims as being unpatentable over Ley in view of Bush, the Applicant argues that the pre-weld diameter of the conductor of Ley is not greater than the depth of the groove of Ley, but rather it is "the outer insulation of the filar that has a diameter greater than the groove width." The Applicant further argues that "the outer insulation becomes stripped away as the filar is forced into the groove such that as the insulation of the filar is removed and electrical connection is

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made between the filar and the groove." Finally, the Applicant argues that the filar itself has a diameter that is equal to the depth of the groove and reproduces the following figure:



In the figure above, the Applicant contends that the diameter of the filar A is equal to the depth of the groove B. However, diameter A is an inner diameter of the filar. If inner diameter A is equal to depth B, then an outer diameter of the filar would be greater than the depth of the groove B. The Examiner respectfully submits that "a pre-weld diameter" as claimed may be an outer diameter of the filar, wherein Ley would disclose the invention as claimed. Furthermore, a pre-weld diameter may also be the diameter

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of the conductor 106 prior to any of the insulation being stripped away. As such, Ley discloses the invention as claimed.

22. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969. In this case, the combination of the disclosure of Ley and Bush would suggest to one of ordinary skill in the art at the time of the invention that it would have been desirable to modify the invention of Ley to include a resistance weld between the conductor and component in order to minimize the bulk of the connection between these two elements. As such, the Examiner considers the rejection to stand.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMMIE HELLER whose telephone number is (571)272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Supervisory Patent Examiner, Art Unit 3766

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Examiner, Art Unit 3766